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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/582,442 06/26/00 NISHIDA

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EXAMINER

TRUONG, T

ART UNIT

PAPER NUMBER

1624

DATE MAILED:

09/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/582,442

Applicant(s)

NISHIDA ET AL.

Examiner

Tamthom N. Truong

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-9,11 and 16-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8 and 9 is/are allowed.
- 6) ☒ Claim(s) 1,2,5-7,11 and 16-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5,8,12 6) ☐ Other: _____

DETAILED ACTION

Applicant's amendment filed on 7-12-01 has been fully considered. While the amended claims have overcome the rejection of "Improper Markush", and 112/2nd for claims 11-14, it has not overcome the 112 rejections for "cyclic amino group". Thus, the previous 112 rejections for said term are maintained herein along with new 112 rejections.

Claims 3, 4, 10, and 12-15 have been cancelled. Therefore, only claims 1, 2, 5-9, 11, 16 remain for consideration along with new claims 17-18.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1, 2, 5-7, 11, and 16-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

a. Applicant's argument that the term "cyclic amino group" is well understood by one skilled in the art, and thus, it is not indefinite. However, the definition of said term cannot be found in any chemical dictionary or textbook. Furthermore, the scope of said term is unduly broad. One skilled in the art cannot tell what rings or ring systems are

included or excluded from the claims. That is, it is unclear if said term refers to a monocycle or polycycle, or if said term includes other heteroatoms in the ring.

b. The terms “aryl” and “heteroaryl” are not precise and definite enough to provide a clear-cut indication of the scope of the subject matter embraced by the claim. That is, when Q is an aryl or heteroaryl, it is unclear if Q is a monocycle, a polycycle, and/or how many heteroatoms are in such a ring.

c. The proviso in claim 1, “R₆, when combined to the carbon atom to which it is bound, may represent R_{6a}-C-R_{6b},...”, sound like a fused ring or spiro ring is intended. However, the definition of R_{6a} and R_{6b} does not seem to allow for a ring. Thus, said proviso is unclear and indefinite.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1, 2, 5-7, 11, and 16-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds with Q as naphthalene, does not reasonably provide enablement for compounds with Q as other aryl or heteroaryl ring. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The scope of “aryl” and “heteroaryl” intends for rings that are beyond “naphthalene” which is

the only ring system for Q that has enablement. The disclosure does not suggest starting materials for Q as another ring or ring system. Thus, one skilled in the art will have to carry out undue experimentation to determine what starting materials to use for making compounds wherein Q is a ring other than naphthalene.

Likewise, the disclosure does not provide sufficient enablement for R₁ as a “cyclic amino group”. The term “cyclic amino group” does not even refer to a particular group or ring either. There is no starting material for such a group suggested in the disclosure either. So, again one skilled in the art will have to carry out undue experimentation to make and use compounds with R₁ as a cyclic amino group.

3. Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating a disease for which FXa is indicated, does not reasonably provide enablement for preventing such a disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The scope of said claims reads on diseases not yet known to be caused or affected by FXa, thus even to treat such diseases would require undue experimentation, let alone preventing them. The skilled scientists must first determine which diseases related to FXa, which calls for further research. Thus, to prevent such diseases, one would have to determine the onset of therapy, patient types, predisposing factors, all of which are not disclosed herein. Given the unpredictable nature of the art, the skilled scientist will have to carry out undue experimentation to prevent such a disease.

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Allowable Subject Matter

Claims 8 and 9 are allowable since said claims are drawn to species which are not found in any of the references of record.

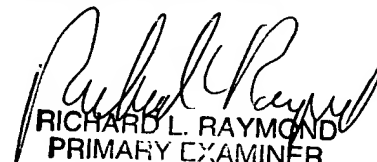
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 703-305-4485. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


T. Truong

September 24, 2001


RICHARD L. RAYMOND
PRIMARY EXAMINER
ART UNIT 1624